UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

ERIC ANTHONY NEPUTE,
individually, and as
Owner of Quickwork LLC; and

QUICKWORK LLC,
a limited liability company,
also d/b/a WELLNESS WARRIOR,

Defendants.

Case No.: 4:21-cv-00437

MEMORANDUM IN SUPPORT OF THE UNITED STATES' MOTION TO EXCLUDE DEFENDANTS' EXPERTS

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I. INTRODUCTION

To substantiate Defendants' claims that Vitamin D and Zinc can treat or prevent COVID-19, Defendants have proffered three experts: Dr. Christina Parks, Dr. Michael Holick, and Defendant Eric Nepute himself. Specific portions of these proffered experts' testimony should be excluded on several grounds. *First*, Dr. Parks and Nepute are unqualified to offer opinions that Zinc or Vitamin D can prevent or treat COVID-19. Dr. Parks is a middle- and high-school science teacher who obtained her Ph.D in 1999, has not conducted formal research since 2000, and, even when she was academically active, did not conduct research into whether compounds could prevent or treat disease. Nepute is not a medical doctor, and his daily chiropractic practice does not typically involve treatment of patients with infectious diseases. *Second*, Drs. Parks and Holick are unqualified to offer expert opinions as to how consumers would interpret Nepute's claims, because they lack the specialized expertise to do so. *Third*, Dr. Parks and Nepute have failed to adequately articulate a reliable methodology to reach the conclusion that Zinc can prevent or treat COVID-19, because they have not adequately explained how, if at all, they weigh conflicting evidence from different study designs. Accordingly, the United States requests that the Court exclude the expert testimony of Dr. Parks and Nepute in their entirely, and Dr. Holick in part.

II. BACKGROUND

A. The United States' Claims

In this suit, Plaintiff United States of America alleges that Defendants Eric Nepute and Quickwork LLC violated the Federal Trade Commission Act, 15 U.S.C. §§ 45, 52, and the COVID-19 Consumer Protection Act, Pub. L. No. 116-260, Title XIV, § 1401 ("COVID-19 Act"), by deceptively advertising that their Wellness Warrior Vitamin D and Zinc supplements can treat

or prevent COVID-19. *See* Compl., ECF No. 1, at ¶¶ 73, 75, 81, 83.[1]

To establish that Defendants committed these violations, the United States must show, among other elements, that Defendants' representations are "likely to mislead consumers acting reasonably under the circumstances." *FTC v. Pantron I Corp.*, 33. F.3d 1088, 1095 (9th Cir. 1994). A representation is likely to mislead a reasonable consumer if it is false, or if the advertiser "lacked reasonable basis—or adequate substantiation—for asserting that the representation was true." *FTC v. Real Wealth, Inc.*, No. 10-0060-CV-W-FJG, 2011 WL 1930401, at *3 (W.D. Mo. May 17, 2011); *see also POM Wonderful, LLC v. FTC*, 777 F.3d 478, 490 (D.C. Cir. 2015). To show the advertiser lacked a "reasonable basis" for particular claims, the United States must "(1) demonstrate 'what evidence would in fact establish such a claim in the relevant scientific community'; and (2) 'compare the advertisers' substantiation evidence to that required by the scientific community to see if the claims have been established." *FTC v. Direct Marketing Concepts, Inc.*, 624 F.3d 1, 8 (1st Cir. 2010) (quoting *Removatron Intern. Corp. v. FTC*, 884 F.2d 1489, 1498 (1st Cir. 1989)).[2]

[1] It also alleges that Defendants violated these laws by deceptively advertising that their Vitamin D and Zinc supplements can treat or prevent COVID-19 more effectively than the currently available vaccines. *See id.* at ¶¶ 74, 82. None of Defendants' experts opine that Vitamin D or Zinc can treat or prevent COVID-19 more effectively than the currently available vaccines. *See* Ex. 2 (Parks Tr.) at 55:8-10, 16-21; Ex. 8 (Holick Tr.) at 54:10-13, 55:7-56:1; Ex. 5 (Nepute Rep.) at pp. 1-3 (identifying opinions).

[2] FTC has "substantial expertise" in "assessing whether advertisements are misleading or deceptive," and that expertise is worthy of deference from the Court. *Thompson Med. Co. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986). Applying its expertise, FTC distinguishes between "efficacy claims" (i.e., that a product can treat a disease) and "establishment claims" (i.e., that it is scientifically proven that a product can treat a disease). But both types of claims require consideration of whether the advertiser possesses evidence that would satisfy the experts in the relevant scientific community. *See POM Wonderful*, 777 F.3d at 491.

Consequently, to prove its claims, the United States must show, among other things, that Defendants lacked evidence sufficient to satisfy the relevant scientific community—in short, competent and reliable scientific evidence—that Vitamin D and Zinc can treat or prevent COVID-19.

B. The Experts

To establish that Defendants lack such competent and reliable scientific evidence, the United States will offer the expert testimony of Dr. Erik Dubberke, a Professor of Medicine at Washington University in St. Louis, and Medical Director of Infection Prevention and Control at Missouri Baptist Medical Center. *See* Ex.[3] 1 (Dubberke Rep.) at ¶ 1. After reviewing the relevant literature, Dr. Dubberke opines that experts in his field would require well done, double-blind, randomized controlled trials demonstrating therapeutic benefit to support claims that Vitamin D and Zinc could treat or prevent COVID-19, *see id.* at ¶ 29; that the best-done such studies have not demonstrated therapeutic benefit for either compound, *see id.* at ¶ 30; that based on the best available evidence, none of the National Institutes of Health, Centers for Disease Control and Prevention, Infectious Disease Society of America, Endocrine Society, World Health Organization, or European Centers for Disease Control and Prevention recommends either compound for the prevention or treatment of COVID-19, *see id.* at ¶ 31; and, consequently, that there is no competent and reliable evidence that Vitamin D or Zinc can treat or prevent COVID-19, *see id.* at ¶ 7(a).

In response, Defendants have offered three experts: Christina Parks, Michael Holick, and Nepute himself.

Christina Parks. Dr. Parks is currently a middle- and high-school science teacher for a

[3] The United States provides a table with full descriptions of the exhibits cited in this memorandum in its Motion to Exclude Defendants' Experts.

homeschool cooperative. Ex. 2 (Parks Tr.) at 34:9-13. She seeks to offer five opinions:

1. "After careful review of the Exhibits detailing Dr. Nepute's statements regarding the advertisement of zinc, I found the government's allegations that Dr. Nepute claimed that zinc could be used to prevent and/or treat COVID to be misleading to the point of error." *See* Ex. 3 (Parks Rep.) at 3-5;

2. "[T]here is competent and reliable scientific evidence that zinc is beneficial to the human immune system and prophylactic use with 'boost' immunity." *Id.* at 5-8; *see also* Ex. 2 (Parks Tr.) at 90:24-91:5;

3. "[T]here is competent and reliable scientific evidence that zinc helps the immune system's anti-viral response." Ex. 3 (Parks Rep.) at 8-10;

4. There is competent and reliable scientific evidence that "zinc can reduce the risk of SARS CoV—2 infection." *Id.* at 10-12; and

5. There is competent and reliable evidence that "zinc can improve outcomes in COVID-19 patients." *Id.* at 12-14.

Michael Holick. Dr. Holick is a professor at Boston University School of Medicine. He seeks to offer opinions relating to Vitamin D's therapeutic benefits. As relevant here, he seeks to testify that he "was unable to correlate the Defendants' statements in the record [he] reviewed with the government's characterization of those statements." Ex. 4 (Holick Rep.) at ¶ 35.

Eric Nepute. Nepute is a Missouri chiropractor. He seeks to opine that there is competent and reliable scientific evidence that: (1) Vitamin D and Zinc can help strengthen or boost the immune system; (2) Vitamin D and Zinc can reduce the risk of infection with COVID-19; and (3) Vitamin D and Zinc can improve outcomes for COVID-19 patients. *See* Ex. 5 (Nepute Supplemental Disclosure) at p.2. He also seeks to opine that he has an obligation under the Hippocratic Oath to recommend vitamin D and Zinc. *See id.*

Like Dr. Dubberke, Defendants' experts' opinions are based on their identification and analysis of medical literature addressing these topics (with the exception of Drs. Holick and Parks' opinions regarding their interpretation of Nepute's statements).

III. LEGAL STANDARD

"Federal Rule of Evidence 702 governs the admissibility of expert testimony, and under this rule the district court is vested with a gatekeeping function, ensuring that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *In re Bair Hugger Forced Air Warming Devices Prod. Liab. Litig.*, 9 F.4th 768, 776-77 (8th Cir. 2021) ("*Bair Hugger*") (internal quotations omitted); *see generally Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). For expert testimony to be admissible, it must (i) "be useful to the finder of fact in deciding the ultimate issue of fact, meaning it must be relevant"; (ii) "the expert must be qualified to assist the finder of fact"; and (iii) "the testimony must be reliable or trustworthy in an evidentiary sense." *Id.* at 777. Because Defendants are "proponent[s] of the expert testimony in question," they "have the burden to prove it admissibility by a preponderance of the evidence." *Id.* at 776.[4]

IV. ARGUMENT

The Court should exclude the testimony of Dr. Parks and Nepute in its entirety, and of Dr. Holick in part, because (A) Dr. Parks and Nepute lack the appropriate training and experience and are therefore not qualified to testify regarding the therapeutic benefits of Vitamin D or Zinc; (B) Dr. Parks and Dr. Holick are not qualified to provide an expert opinion of how reasonable consumers would interpret Nepute's statements; and (C) Dr. Parks and Nepute did not apply a reliable methodology to reach their conclusions.

A. Dr. Parks and Nepute Are Entirely Unqualified To Testify Regarding The Therapeutic Benefits Of Vitamin D Or Zinc

Rule 702 requires an expert to be qualified by "knowledge, skill, experience, training, or education." "The Eighth Circuit when applying the *Daubert* standard requires that a proposed

[4] The United States reserves its right to challenge the admissibility of Defendants' proffered expert testimony under any rule of evidence other than Rule 702 via motion *in limine*.

expert have formal training in the area he is called to testify about or, at the minimum, some practical knowledge or experience that would provide him the necessary expertise in that area." *Housley v. Orteck Int'l, Inc.*, 488 F. Supp. 2d 819, 825 (S.D. Iowa 2007) (citing cases).

1. Dr. Parks Is Unqualified To Testify As To The Clinical Benefits Of Zinc

The bulk of Dr. Parks' opinion relates to the clinical benefits of Zinc: she seeks to testify that Zinc boosts the immune system, inhibits viral replication, can reduce the likelihood of COVID-19; and improves outcomes for COVID-19 patients. *See* Ex. 3 (Parks Rep.) at 5-15.

Dr. Parks lacks the necessary qualifications to offer these opinions. She is currently a middle school and high school science teacher for a homeschool cooperative. *See* Ex. 2 (Parks Tr.) at 34:9-13. With the exception of a consulting firm that she started last year, teaching middle and/or high school students has been her sole employment since 2004. *See* Ex. 6 (Parks Resume) at 1.[5]

Dr. Parks lacks relevant medical experience. She is not a physician. Ex. 2 (Parks Tr.) at 19:22-23. She has not "receive[d] training and education in the evaluation or treatment of medical patients." *Id.* at 20:1-4. She has not treated any patient for any infectious disease, including COVID-19. *Id.* at 20:7-11. She has "never led a clinical trial of any kind." *Id.* at 20:5-6. Nor has she "developed protocols for the treatment of disease in the community." *Id.*at 22:4-7.

Dr. Parks also lacks appropriate education and training. While Dr. Parks has a Ph.D in cellular and molecular biology, she earned that degree in 1999. *Id.* at 11:23-25. In her academic career, she participated in the writing of only six peer-reviewed studies, and was the primary author of only one. *Id.* at 30:24-31:2. She has not written a peer-reviewed publication since 2000, the year after she earned her Ph.D. *id.* at 30:20-23. None of the research that she did "during [her] PhD program focuse[d] on identifying or evaluating compounds for use in the treatment of disease." *Id.*

[5] Dr. Parks served as a textbook editor from 2000-2003. *Id.*

at 19:7-10. And none of that research related to Zinc or any dietary supplement: even when she was active academically, she did not perform research as to whether Zinc or any other compound could prevent or treat any disease. *Id.* at 19:7-10, 19-21.

Dr. Parks lacks the necessary personal expertise or experience with Zinc. Accordingly, she based her opinions—generated solely for this litigation—on her review and analysis of medical literature. *See Id.* at 58:8-12; *Cf. Lauzon v. Senco Prod., Inc.*, 270 F.3d 681, 693 (8th Cir. 2001) (expertise developed for litigation weighs against admission). For her opinion to be reliable, her ability to correctly identify and analyze the relevant medical literature is essential. But, again, she lacks the training and experience to evaluate the relevant clinical data and whether it supports the conclusion that a compound can prevent or treat a disease. *See In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007) ("*Bextra*") (excluding expert "with no relevant research experience and who developed his opinion for the purposes of testifying").

"The main purpose of *Daubert* exclusion is to protect juries from being swayed by dubious scientific testimony." *In re Zurn Pex Plumbing Prod. Liab. Litig.*, 644 F.3d 604, 613 (8th Cir. 2011). That purpose counsels exclusion of Dr. Parks' opinions here. *See Garnac Grain Co. v. Blackley*, 932 F.2d 1563, 1566 (8th Cir. 1991) (precluding nonaccountants without formal accounting training from testifying regarding accounting standards); *Froemming v. Gate City Fed. Sav. & Loan Ass'n*, 822 F.2d 723, 732 (8th Cir. 1987) (precluding expert without relevant experience from testifying).

2. Nepute Is Unqualified To Testify As To The Clinical Benefits Of Vitamin D Or Zinc

Nepute is similarly unqualified to offer his proposed opinions regarding the clinical benefits of Vitamin D and Zinc, because he lacks the relevant medical expertise.

As noted above, to determine whether a claim is adequately substantiated, one must consider the evidence that the relevant scientific community would require to establish that claim. *Supra* at Part II.A. (citing cases). The relevant scientific community here, however specifically defined, includes individuals engaged in the practice of medicine, clinical drug development, or evaluation of clinical data—because those are the individuals who assess the quality of clinical evidence to determine whether compounds can prevent or treat diseases.

Nepute is a chiropractor. He did not attend medical school, and by his own admission, does not practice medicine. Ex. 7 (Nepute Tr.) at 47:18-20, 98:9-12. Indeed, were he to do so, he would violate Missouri state law. *See* Mo. Ann. Stat. § 331.060(2)(19). He is not permitted to write prescriptions; were he to do so, that would also violate state law. *See id*; *see also* Ex. 7 (Nepute Tr.) at 50:1-16. He has not led or participated in any clinical trials. *Id*. at 28:20-25. And he has not published any academic papers in any peer-reviewed journal. *Id.* at 53:1-3.

Further, Nepute's practice does not primarily focus on treatment of infectious diseases. To the contrary, at his practice, "neuromusculoskeletal [complaints] and fatigue are the main things" that he sees—"probably 80 percent, maybe 85 percent of people that come through the door have a neuromusculoskeletal complaint and dysfunction." *Id*. at 66:10-17. He also provides "nutritional care." *Id.* at 65:21-4. These services, while valuable, do not require him to conduct assessments of the clinical efficacy of compounds to prevent or treat disease.

Accordingly, Nepute's lack of relevant training and experience exclude him from the relevant scientific community. This is particularly so because his conclusions conflict with those scientific societies and agencies whose core competencies include the evaluation of whether compounds can prevent or treat disease—including the NIH, CDC, Infectious Disease Society of America, Endocrine Society, WHO, and European Centers for Disease Control and Prevention—

each of which has declined to recommend Vitamin D or Zinc for the treatment of COVID-19, and each of which would unquestionably fall within the relevant scientific community. *See* Ex. 1 (Dubberke Rep.) at ¶ 31. Accordingly, he is unqualified to testify regarding what level of evidence is necessary to substantiate such claims. *See Garnac Grain*, 932 F.2d at 1566; *See also Bextra*, 524 F. Supp. 2d at 1176 (medical professional unqualified to offer general causation testimony because he lacked "specialized epidemiology training", had only published on topics "unrelated to subject matter of [the] lawsuit, and had "never participated in an observational study of any kind").

B. Dr. Parks and Dr. Holick Are Not Qualified To Provide an Expert Opinion On How Reasonable Consumers Would Interpret Nepute's Statements

Dr. Parks also seeks to testify that, based on her review of certain of Nepute's statements, the "government's allegations that Nepute claimed that zinc could be used to prevent and/or treat COVID to be misleading to the point of error." Ex. 3 (Parks Rep.) at 3-4. Similarly, Dr. Holick seeks to testify that he "was unable to correlate the Defendants' statements [regarding Vitamin D and COVID-19] in the record [he] reviewed with the government's characterization of those statements." Ex. 4 (Holick Rep.) at ¶ 35. Both are unqualified to offer these opinions.

"An expert may proceed as far as—but no further than—his specialized knowledge assists him in going." *Hirchak v. W.W. Grainger, Inc.*, 980 F.3d 605, 609 (8th Cir. 2020). Dr. Parks does not claim any specialized knowledge in determining how a reasonable consumer would interpret particular statements. As she acknowledges, she does not have "any particular expertise in interpreting advertising claims." Ex. 2 (Parks Tr.) at 87:12-14. Nor has she "ever been hired to assess the meaning of an advertising claim." *Id.* at 87:15-17. And, in formulating this opinion, she does not "cite any scientific papers or literature"—her claimed area of expertise. *Id.* at 87:4-7. For his part, Dr. Holick acknowledged that he had never offered expert testimony or been qualified as an expert to testify "specifically about how consumers interpret particular marketing plans;" Ex. 8

(Holick Tr.) at 247:14-20; and that he "did not have the expertise" necessary to "evaluate how a consumer would interpret a particular marketing claim." *Id.* at 247:21-248:4.

Whatever scientific expertise Drs. Parks and Holick may have, it is not in evaluating advertising or marketing claims, and they are not qualified to offer expert opinions on those issues. *See FTC v. Washington Data Res.,* No. 8:09-CV-2309-T-23TBM, 2011 WL 2669661, at *2 (M.D. Fla. July 7, 2011) (excluding expert from testifying regarding consumer's interpretation of marketing claim because "conclusion as to the perception of a 'reasonable consumer' appears purely speculative, apart from any scientific or technical knowledge or method, and unhelpful because [it rested entirely on expert's] unlearned prediction.").

Moreover, "courts must guard against invading the province of the jury on a question which the jury was entirely capable of answering without the benefit of expert opinion." *Am. Auto. Ins. Co. v. Omega Flex, Inc.*, 783 F.3d 720, 725 (8th Cir. 2015) (citation omitted). The jury and the Court are capable of reviewing Nepute's statements and determining whether they expressly or impliedly convey the net impression that Vitamin D and Zinc treat or prevent COVID-19—the pertinent question here. *See FTC v. Nat'l Urological Grp.*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008), *aff'd*, 356 F. App'x 358 (11th Cir. 2009). Their opinions are "no better than another person's opinion." *Washington Data Res.*, 2011 WL 2669661, at *2. They should be excluded.

C. Dr. Parks' and Nepute's Opinions That Zinc Can Treat Or Prevent COVID-19 Should Be Excluded Because They Have Not Articulated A Reliable Methodology

Dr. Parks and Nepute both seek to testify that Zinc can reduce the risk of infection from COVID-19 and improve treatment outcomes in COVID-19 patients. These opinions suffer from the same fundamental flaw in methodology: they fail to explain how they distinguished between high quality randomized controlled trials, on the one hand, and less valuable observational and *in vitro* studies, on the other, in reaching their opinion. As a result, there is no way for the Court to

assess whether their methodologies, and thus their opinions, are reliable. Dr. Parks' and Nepute's opinions must therefore be excluded.

1. It Is Generally Accepted That Randomized Controlled Trials Are Highest Quality Evidence For Determining Whether Use of A Compound Can Cause A Health Outcome

Examining the flaws in Dr Parks' and Nepute's opinions requires a brief discussion of the different study types commonly used to test the relationship between a compound and a health outcome.

Randomized Controlled Trials. The first, and highest quality, is the randomized controlled trial ("RCT"):

> To determine whether an agent is related to the risk of developing a certain disease or an adverse health outcome, we might ideally want to conduct an experimental study in which the subjects would be randomly assigned to one of two groups: one group exposed to the agent of interest and the other not exposed. After a period of time, the study participants in both groups would be evaluated for the development of the disease. This type of study, called a randomized clinical trial, or true experiment, is considered the gold standard for determining the relationship of an agent to a health outcome or adverse side effect. Such a study design is often used to evaluate new drugs or medical treatments and is the best way to ensure that any observed difference in outcome between the two groups is likely to be the result of exposure to the drug or medical treatment.

Ex. 9 (Federal Judicial Center, *Reference Manual on Scientific Evidence* at 555 (3d ed. 2011) ("FJC Manual")); *see also Bair Hugger*, 9 F.4th at 779-780 & ns. 3-5 (citing FJC Manual). Courts consider the RCT the gold standard for determining whether a compound causes a particular health outcome. *See, e.g.*, *Bextra*, 524 F. Supp. 2d at 1173. So too does the FDA. *See* Ex. 10 (FDA, Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims, Docket No. FDA-2007-D-0371 (Jan. 2009)) ("FDA Guidance") at p. 4 ("Randomized controlled trials offer the best assessment of a causal relationship between a substance and a disease because they control for known confounders of results (i.e., other factors that could affect risk of disease.)"). And so too does Dr. Parks herself. *See* Ex. 2 (Parks Tr.) at 80:19-23) ("we do

use randomized, controls trials as the gold standard for evaluating drugs for safety and efficacy").

Observational Studies. By contrast, "[o]bservational studies measure associations between the substance and disease." Ex. 10 (FDA Guidance) at 4. Here, relevant observational studies could look at, for example, two groups with differing Zinc blood levels, and compare whether those groups had different rates of COVID-19 infection, hospitalization, or death. Importantly, however, the "Achilles' heel of observational studies is the possibility of differences in the two populations being studied with regard to risk factors other than exposure to the agent" (here, differences in COVID-19 outcomes due to factors other than Zinc). Ex. 9 (FJC Manual) at 556. "By contrast, experimental studies, in which studies are randomized, generally avoid this problem." *Id.*; *see also* Ex. 10 (FDA Guidance) at 4 ("In contrast to intervention studies, observational studies cannot determine whether an observed relationship represents a relationship which the substance caused a reduction in disease risk or is a coincidence.") (citation omitted).

In Vitro Studies. Third, researchers may conduct *in vitro* studies, "in which human or animal tissue or cells are grown in laboratories and are exposed to certain substances." FJC Manual at 564. "The problem with this approach is . . . extrapolation—whether one can generalize the findings from the artificial setting of tissues in laboratories to whole human beings." *Id*. "In vitro studies are conducted in an artificial environmental and cannot account for a multitude of normal physiological processes such as digestion, absorption, distribution, and metabolism . . . ." FDA Guidance at p. 5. "These studies do not provide information from which scientific conclusions can be drawn regarding a relationship between the substance and disease in humans." *Id*. Dr. Parks agrees. Ex. 2 (Parks Tr.) at 79:14-17 (in vitro study generally cannot "establish causation . . . of a clinical effect of a substance in the human").

In sum, it is generally accepted that RCTs are the most valuable for assessing whether a compound can prevent or treat a medical condition; observational and *in vitro* studies are not designed to do so. Thus, in evaluating the clinical evidence relating to Zinc's ability to prevent or treat COVID-19, RCTs are of paramount importance. *See Bair Hugger*, 9 F.4th at 777 (general acceptance of methodology is factor in assessing evaluating reliability).

2. Dr. Parks and Nepute Fail To Articulate A Methodology That Adequately Accounts For The Different Value Of Different Study Designs

In their opinions, Dr. Parks and Nepute fail to explain whether and how they weighed the differing evidentiary value of different study designs in reaching their opinions. Both indiscriminately cite *in vitro*, observational, and RCT studies. Accordingly, both proffered experts fail to explain, what process, if any, they used to account for differing results from RCT, observational, and *in vitro* studies—and in particular, how heavily they weighed the results of RCTs that found Zinc had no effect as a COVID-19 therapeutic. Because Dr. Parks and Nepute failed to provide this explanation, there is no way for the Court to assess whether their methodology has been tested, subjected to peer review and publication, has a high error rate, or enjoys general acceptance, as required by law. *See Bair Hugger*, 9 F.4th at 777.[6]

Dr. Parks' treatment of particular RCTs is illustrative of this problem. She opined that Zinc can "improve outcomes in COVID-19 patients." Ex. 3 (Parks Rep.) at 14. But she stated that was

[6] While the Eighth Circuit admitted general causation testimony on the basis of observational studies in *Bair Hugger*, the case does not support admissibility here. In *Bair Hugger*, Plaintiff's general causation experts sought to offer the opinion that the defendant's medical device was capable of causing certain infections during surgery, 9 F.4th at 766. In reaching their opinions, the experts relied on an epidemiological study reporting an association between the device and infections, and studies and reports supporting mechanistic theories of causation. *Id*. at 778. The Eighth Circuit, however, was not presented with, and therefore did not assess, any RCT evidence. The Eighth Circuit therefore had no occasion to address whether the relevant experts had a reliably articulated methodology for comparing the results of conflicting RCTs and less valuable studies.

unaware of any "randomized, control studies that show that zinc supplementation used as a treatment in COVID patients improves outcomes." Ex. 2 (Parks Tr.) at 177:20-24. In so testifying, she disregarded at least two RCTs (that were specifically cited by Dr. Dubberke) that concluded that Zinc supplementation did *not* improve COVID-19 outcomes for certain patients. *See* Ex. 11 (Thomas *et al.*) at 1 ("[t]hese findings suggest that treatment with zinc, ascorbic acid, or both does not affect SARS-CoV-2 symptoms"); Ex. 12 (Abd-Elsalam *et al.*) at 1 ("Zinc supplements did not enhance the clinical efficacy of [hydroxychloroquine]" in treating COVID-19.). When shown the Thomas study, she testified that she "did not place significant weight on it" without adequately articulating why. Ex. 2 (Parks Tr.) at 182:8-183:4. As a result, there is no way for the Court to assess whether she has a reliable methodology for discounting these studies' results.[7] For his part, when asked "what factors [he consider[ed] in balancing the studies that show a benefit versus those that don't," Nepute testified that he "look[ed] at the whole body of work, [a]nd then [he] look[ed] at the risk verse benefit opportunities, period" without sufficiently articulating how he evaluated different types of studies within the body of work at which he looked. *Id.* at 211:12-212:6.

Because neither expert adequately explains their methodology for comparing conflicting results between RCTs, on the one hand, and lower quality observational and *in vitro* studies, on the other, their opinions are insufficiently reliable and must be excluded. *See Smith v. Bubak*, 643 F.3d 1137, 1141-42 (8th Cir. 2011) (affirming exclusion of expert testimony that medication would improve outcomes for stroke patient because, while cited study "does indicate that [treatment] causes some stroke patients to improve, this result does not reveal whether giving a patient [the

[7] Nepute testified that the Thomas study was a "great study", but that there were "a lot of factors in [it] that we don't know that are really important to look at." Ex. 7 (Nepute Tr.) at 208:12-20.

treatment] will more likely than not cause a stroke patient to improve"); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 886 (10th Cir. 2005) (excluding experts who "ignored or discounted without explanation the contrary epidemiological studies"); *Bextra*, 524 F. Supp. 2d at 1176 (excluding expert who "cherry-pick[ed] observational studies that support his conclusion and reject[ed] or ignore[ed] the great weight of the evidence that contradicts his conclusion"); *see also In re Neurontin Marketing & Sales Practices Litig.*, No. CIV.A. 04-CV10981PBS, 2010 WL 559108, at *1 (D. Mass. Feb. 12, 2010) ("expert who does not give appropriate weight to [RCTs] in rendering an opinion on a drug's effectiveness or who ignores negative [RCTs] flunks the *Daubert* test of reliability.").

To be clear, the methodological flaw in these expert opinions is *not* that they rely on observational and *in vitro* studies in reaching their conclusions. It is the failure to explain how, if at all, they "work[ed] to bridge the gap between association and causation." *Bair Hugger*, 9 F.4th at 779. This explanation is essential because, as noted above, *in vitro* and observational studies are not designed to assess whether a compound *causes* a particular health outcome—the relevant question in this dispute. And without this explanation, a juror would simply have to take the expert on faith in order to find the Defendants' had reasonable substantiation for their claims. This is precisely the sort of guesswork that renders an expert's opinion unreliable, and the sort of expert testimony that Rule 702 was designed to preclude. *See Bubak*, 643 F.3d at 1141-42.

V. CONCLUSION

For the foregoing reasons, the United States respectfully asks this Court to exclude Dr. Parks' testimony and Nepute's testimony entirely; and to exclude Dr. Holick from testifying regarding his interpretation of Nepute's statements.

Dated: September 2, 2022

Respectfully submitted,

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